

### Remarks

Claims 36-56 are pending in the application. Claims 36, 45, 49-51, and 55 has been amended and claim 56 has been added. Applicant believes these amendments serve to clarify the present invention and are independent of patentability. No new matter has been added.

#### Specification

The abstract has been replaced to address the Examiner's objections. The title has also been changed to reflect the claimed invention.

The specification has been amended to correct inconsistencies between the specification and the drawings. Specifically, the specification has been amended to provide proper reference to Figures 14A-14G, 17A-17B, 18, and 19A-19B. No new matter has been added.

#### 35 U.S.C. §112 Rejection

Claims 36-55 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner states:

Applicant mentions in passing on page 3, line 18-20 of the specification, that the device may be used to remove fetal tissue. However, there is no further mention of the fetal tissue and how to use it. There is no statement that fetal tissue may be implanted. There is no statement that *any* tissue should be removed from a first human and implanted in a second human. In fact, applicant states repeatedly, "Human tissue grafting works best using the patient's own tissue as donor material." Furthermore, the particular manner in which fetal tissue is removed is not supported in the specification, i.e., "moving the separated portions of the fetal tissue along a passage under the influence of suction."

For the reasons set forth below, Applicant respectfully disagrees and submits that the claims 36-55 are fully supported by the specification.

An objective standard for determining compliance with the written description

requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989). To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375 (Fed. Cir. 1983)). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). MPEP § 2163.02.

The present invention teaches the concept of cutting and removing selected portions of tissue from a donor and implanted these portions into a patient. Applicant contends that the term "tissue" is genus for many types of body tissue. Applicant's invention contemplates the use of different tissue types to form grafts. Throughout the specification, Applicant mentions different types of tissue, for example, "The invention is not limited to the removal of bone tissue and may be used for removal of cartilage, muscle, fetal tissue, etc." (Page 3, lines 18-20). "It should be understood that the present invention is not limited to the removal of bone tissue, but is useful in the removal of any hard or soft tissue in the body." (Page 11, lines 20-23).

Accordingly, Applicant submits the specification uses descriptive wording to clearly allow persons of ordinary skill in the art to recognize that the present invention teaches the concept of cutting and removing a selected portion of fetal tissue from a donor and implanted the tissue into a patient.

Additionally, the present invention discloses a working example for the removal and implantation of body tissue, wherein bone tissue is used only as an exemplary tissue, in which the particular manner in that the tissue is removed is disclosed. Specifically, the tissue is drawn

through the suction passage in the flexible drive shaft and thence into the suction line. (Page 13, lines 3-5). Accordingly, Applicant submits that the particular method in which the fetal tissue is removed is supported in the specification.

Furthermore, the Examiner stated that there is no statement that any tissue should be removed from a first human and implanted in a second human. In response, Applicant has amended claim 36 to claim the tissue is removed from a donor and implanted into a patient. The amendment to this claim is support by the specification, see ,e.g. page 1, lines 7-10; page 8, line 1; and page 8, lines 3-4.

Applicant agrees that the specification describes a preferred embodiment in which portions of tissue are removed from a donor and ultimately re-implanted into the donor. However, the specification is clear that this is only a preferred embodiment. (*See, e.g.* page 2, line 26 to page 3, line 2; page 7, lines 7-10; page 21, lines 7-12). Case law also is clear that “[i]t is a truism that a claim need not be limited to a preferred embodiment.” *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473 (Fed. Cir. 1998). Thus, Applicant respectfully submits that the specification fully supports and describes removal of portions of tissue from a donor and implantation into a patient, with the donor and patient being different individuals.

In light of the foregoing, Applicant respectfully submits that the specification clearly allow persons of ordinary skill in the art to recognize that applicant invented what is claimed. Applicant submits that the specification teaches different types of body tissue, including fetal tissue, and a method of removing the tissue. Accordingly, Applicant submits that 35 U.S.C. § 112 rejections of claims 36-55 are not supported and should be withdrawn.

### 35 U.S.C. §103 Rejection

Claims 36, 37, 39, and 53 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,401,759 to Dunnett et al. (“Dunnett”) in view of U.S. Patent No. 3,769,980 to Karman (“Karman”). Specifically, the Examiner states that Dunnett discloses implanting human fetal tissue in a human body but does not disclose how the tissue was retrieved. Karman discloses one way of removing human fetal tissue from a human body by cutting and sucking. Therefore, it would have been obvious to one of ordinary skill in the art at

the time the invention was made to remove human fetal tissue from a human by cutting and sucking in order to implant it into a human body.

For the reasons set forth below, Applicant respectfully submits that the rejected claims are not taught or suggested by the references, either alone or in combination.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *see* MPEP § 2143. If an independent claim is nonobvious under 35U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988); *see* MPEP § 2143- § 2143.03.

The initial burden is on the Examiner to provide some suggestion of the desirability of doing what the inventor has done. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985).

Dunnett discloses a method of enhancing vascularization and growth of neural grafts in warm-blooded animal. (Abstract). Specifically, Dunnett discloses using nimodipine for increasing the survival and growth of neural transplants. (Column 1, lines 11-16). The donor tissue for the neural graphs is described, for example, as being nigral tissue. (Column 5, lines 43-45). Nigral tissue is the layer of gray substance that separates the posterior parts of the cerebral peduncles (tegmentum mesencephali) from the anterior parts; it includes a posterior compact part with many pigmented cells and an anterior reticular part whose cells contain little. Additionally, peripheral or embryonic central nervous system tissue (Column 6, lines 30-33) and cortical tissue (Column 6, lines 42-43) are disclosed as donor tissue. As disclosed, the donor

tissue is neural tissues and would necessary require a precise and delicate procedure to harvest.

Karman discloses a combination speculum and cannula for suction aspiration in the performance of abortions. (Column 1, lines 6-10). In use, the cannula is inserted though the cervix into the uterus and rotated until the tissue seen through the tubing of the suction aspirator. (Column 6, lines 37-39). There is only a gentle scraping and the tip design prevents application of forces which would damage the uterine walls. (Column 4, lines 39-41). As disclosed, the Karman device is a non-precision device, removing the embryonic material in a non-precise manner.

Initially, to establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Dunnett discloses using neural tissue as the donor tissue, the harvesting of which would necessarily require a precise surgical procedure. The Karman device is a gross surgical device, lacking precision is use, which chaotically removes the totality of the embryonic material.

Accordingly, Applicant submits that there is no suggestion or motivation in either reference to combine the references. Dunnett is a method of using nimodipine to enhance vascularization and growth of neural grafts, where the neural grafts are discloses as neural embryonic materiel. Karman discloses an abortion device. The use of the Karman device would preclude the harvesting of the neural embryonic material.

Additionally, there is no reasonable expectation of success in combining the references. The Karman device suctions the embryonic material for removal, rendering it difficult to harvest neural tissue for grafts. As such, the use of the Karman device to collect the embryonic material would not yield material acceptable for a neural graft for the Dunnett method.

Finally, even if the references were combined as suggested by the Examiner, the claimed invention would still not result. The Examiner stated that Karman discloses edges (Fig. 7) used to cut tissue in a reciprocating motion through a cannula. However, FIG. 7, discloses holes 26 and 28 in the tubing adjacent to the end 23, and substantially opposite to each other. (Column 3, lines 37-40). The angle of the notch which forms the opening and the angle between the upstream edge of the outer wall is less the 90 degrees. (Column 3, lines 56-59). This angle

provides a slight scraping edge at the wall of the tubing. (Column 3, lines 59-61).

As such, Karman does not disclose using the edges to remove tissue in a reciprocating motion. Additionally, if the Karman device contained edges with sufficient sharpness to cut the tissue with a reciprocating motion, the device would necessarily cut and damage the adjacent uterine wall, which is expressly taught against in Karman. Accordingly, Dunnett and/or Karman do not teach or suggest all the claim elements.

In view of the foregoing, Applicant submits that the examiner failed to establish a *prima facie* case of obviousness. Rather, Applicant respectfully submits that the references do not expressly or impliedly suggest the claimed invention and the Examiner has not presented a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. Accordingly, Applicant submits that the 35 U.S.C. § 103(a) rejections of claims 36, 37, 39 and 53 is not support by the cited art and should be withdrawn.

#### New Claim

Applicant has added new claim 56, which depends from claim 36. The subject matter of claim 56 is supported by the specification. For example and as the Examiner has identified, the specification teaches a preferred embodiment in which the donor and the patient are the same individual.

#### Conclusion

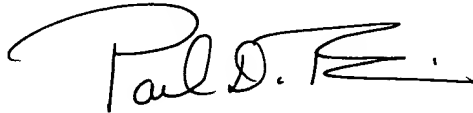
For all of the above reasons, the claim rejections are believed to have been overcome, placing claims 36-56 in condition for allowance, and reconsideration and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned to discuss any matter that would expedite allowance of the present application.

Applicant notes that no prior art was cited against claims 38, 40-52, and 55. In order to expedite prosecution of this case, Applicant has amended claims 45 and 49 to be in independent form. In amending these claims to be in independent form, Applicant has included all the elements of the base claim and addressed the § 112 rejection. Accordingly, Applicant respectfully submits

that amended claims 45 and 49 are now in condition for allowance.

A fee of \$9.00 for one extra claim (at small entity rate) is believed to be due with this submission and a Fee Transmittal Sheet including this fee is submitted concurrently herewith. However, please charge the required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 780-A02-014-7).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul D. Bianco". The signature is fluid and cursive, with a large initial "P" and a stylized "B".

Paul D. Bianco, Reg. # 43,500

Customer Number: 33771  
Paul D. Bianco  
FLEIT KAIN GIBBONS GUTMAN & BONGINI  
601 Brickell Key Drive, Suite 404  
Miami, Florida 33131  
Tel: 305-931-9620; Fax: 305-931-9627  
e-mail: pbianco@focusonip.com